Complete Summary

GUIDELINE TITLE

Hepatitis C virus.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Hepatitis C virus. New York (NY): New York State Department of Health; 2004 Sep. 13 p. [14 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Hepatitis C virus. New York (NY): New York State Department of Health; 2003. 15 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 31, 2008, Erythropoiesis Stimulating Agents (ESAs): Amgen and the U.S. Food and Drug Administration (FDA) informed healthcare professionals of modifications to certain sections of the Boxed Warnings, Indications and Usage, and Dosage and Administration sections of prescribing information for Erythropoiesis Stimulating Agents (ESAs). The changes clarify the FDA-approved conditions for use of ESAs in patients with cancer and revise directions for dosing to state the hemoglobin level at which treatment with an ESA should be initiated.
- January 24, 2008, Leukine (sargramostim): Voluntary market suspension of the current liquid formulation of sargramostim, a granulocyte-macrophage colony-stimulating factor (GM-CSF), because of an upward trend in spontaneous reports of adverse reactions, including syncope (fainting). The lyophilized form of the drug is not affected. See the U.S. Food and Drug Administration (FDA) web site for more information.
- November 8, 2007 and January 3, 2008 Update, Erythropoiesis Stimulating Agents (ESAs): The U.S. Food and Drug Administration (FDA) notified healthcare professionals of revised boxed warnings and other safety-related product labeling changes for erythropoiesis-stimulating agents (ESAs) stating serious adverse events, such as tumor growth and shortened survival in patients with advanced cancer and chronic kidney failure.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Hepatitis C virus (HCV) infection
- Human immunodeficiency virus (HIV) infection

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Gastroenterology
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide recommendations on the prevention, screening, diagnosis, evaluation, treatment, and management of hepatitis C virus in human immunodeficiency virus (HIV)-infected patients

TARGET POPULATION

- Human immunodeficiency virus (HIV) infected patients
- Hepatitis C virus (HCV) infected patients
- HIV/HCV co-infected patients
- Household contacts and sexual partners of HIV and/or HCV infected patients

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention and Counseling

1. Human immunodeficiency virus (HIV) testing and counseling
2. HIV and hepatitis C virus (HCV) risk reduction counseling

Screening and Diagnosis

1. Enzyme-linked immunoabsorbent assay for anti-HCV antibodies (HCV ELISA)
2. Qualitative HCV polymerase chain reaction (PCR)
3. Qualitative and quantitative HCV ribonucleic acid (RNA) assays (not recommended for screening or diagnosis)

Evaluation

1. Substance use and alcohol history
2. Clinical assessment for signs and symptoms of liver disease
3. Laboratory measurements, including
    - Serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT)
    - Prothrombin time
    - Serum albumin
4. Quantitative HCV RNA assay
5. HCV genotype
6. Liver biopsy
7. Screening for hepatitis A and hepatitis B
8. Hepatitis A and/or hepatitis B vaccination
9. Specialist referral

Treatment

1. Pre-treatment:
    - Assess HIV and/or HCV viral loads
    - Complete blood counts
    - Helper cell (CD4) count
    - Thyroid-stimulating hormone
    - Glucose

- Quantitative HCV RNA in serum
- HCV genotype
- Alpha-fetoprotein (only if cirrhotic)
- Pregnancy testing (for female patients)
- Liver biopsy

2. Anti-HCV pharmacotherapy
    - Pegylated interferon alfa (alfa-2a or alfa-2b) plus ribavirin
3. Transplantation (considered for patients with decompensated cirrhosis)

Monitoring

1. Serum ALT
2. HCV RNA assay

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of tests used for screening, diagnosis, and prognosis
- Mortality due to end stage liver disease (ESLD)
- Progression to cirrhosis
- Incidence of hepatocellular carcinoma
- Hepatitis C virus (HCV) viral loads

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person three to four times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Epidemiology and Prevention

- Clinicians should perform human immunodeficiency virus (HIV) testing and counseling in patients with hepatitis C virus (HCV) infection who are not already known to be HIV-infected.
- Regardless of a patient's HIV or HCV infection, clinicians should counsel patients to avoid practices that transmit both HIV and HCV, including high-risk sexual practices and needle-sharing behaviors among injection drug users.
- Clinicians should counsel active injection drug users to use new sterile equipment at all times, dispose of their syringes after one use, and clean their injection sites carefully with clean alcohol swabs. These patients should be urged to undergo treatment to reduce drug use.
- Clinicians should encourage all patients with HCV and all patients with HIV who are sexually active to use condoms.
- Clinicians should advise household contacts of persons chronically infected with HCV to avoid sharing items that may be contaminated with blood such as toothbrushes and razors.
- Clinicians should encourage uninfected, long-term sexual partners of persons co-infected with HCV and HIV to continue to use safe-sex practices to prevent transmission of HIV and HCV.

Screening and Diagnostic Tests

- Clinicians should screen all HIV-infected patients for anti-HCV antibodies as part of the initial evaluation (see Figure 3 in the original guideline document).
- Patients who are currently under care for HIV infection but have never been tested for anti-HCV antibodies should be tested for antibodies, even if they have no evidence of liver disease. If an enzyme-linked immunoabsorbent assay (ELISA) for HCV antibodies is reactive in a patient who does not have known risk factors or evidence of liver disease, HCV infection should be confirmed with a qualitative polymerase chain reaction (PCR) assay.
- A negative HCV ELISA antibody test in HIV-infected patients, particularly those who are severely immunosuppressed (CD4 <100 cells per mm^3), may not exclude HCV and should be followed by a qualitative PCR assay if serum liver enzymes are elevated and the individual has risk factors for HCV exposure.

Evaluating the Patient Co-Infected With HIV and HCV

- Clinicians should obtain a substance use and alcohol history for HIV/HCV co-infected patients.
- Clinicians should advise HIV/HCV co-infected patients and patients infected with HCV alone to discontinue intake of alcohol.
- Clinicians should perform diagnostic testing to determine the presence of HCV viremia and the extent of liver pathology as early as possible for HIV/HCV co-infected patients.
- Baseline evaluation of the HIV/HCV co-infected patient should include a clinical assessment for signs and symptoms of liver disease and baseline laboratory measurements, including serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT), prothrombin time, and serum albumin.

Quantitative HCV ribonucleic acid (RNA) assay and HCV genotype should be performed for those who are candidates for treatment.
- For HIV/HCV co-infected patients who are candidates for treatment and have HCV genotypes 1 and 4, clinicians should obtain a liver biopsy; however, for genotypes 2 and 3, a biopsy may not always be necessary due to higher rates of treatment response.
- Clinicians should screen HIV/HCV co-infected patients and patients infected with either virus alone for immunity to hepatitis A and B. If patients are found to be susceptible to either or both of these viruses, the clinician should vaccinate the patient against hepatitis A and hepatitis B accordingly. Patients who are at increased risk for and non-immune to hepatitis A and hepatitis B infection may be given the combined hepatitis A and B vaccine in a total of three doses at zero, one, and six months.
- Clinicians should refer patients with HCV viremia who are potential candidates for treatment to a specialist with experience in treating hepatitis C in patients with HIV infection or to a clinical trial.

Selecting Patients for Treatment of HCV

- Patients at greatest risk for progression to cirrhosis should be considered candidates for anti-HCV therapy (see Table 5 in the original guideline document).
- The decision to treat should be individualized based on the patient's desire to be treated, his/her immune status, extent of liver damage, HCV and HIV viral loads, risk of adverse effects of treatment, current antiretroviral (ARV) therapy, and absence of contraindications to therapy (see Table 6 in the original guideline document). ARV therapy may need to be modified, delayed, or interrupted to complete an adequate course of therapy for HCV.
- HIV-infected patients with active HCV infection and/or evidence of chronic liver disease who are potential candidates for treatment should be referred to a specialist with experience in treating hepatitis C in patients with HIV infection for evaluation and guidance regarding possible treatment.
- Clinicians should monitor liver pathology in HIV/HCV co-infected patients in whom treatment may be deferred by performing periodic ALT assays; clinicians should consider obtaining a liver biopsy every 3 to 5 years to reassess disease severity in this population.

Treatment of Hepatitis C Infection

- Treatment for HCV should be considered for all patients co-infected with HIV and HCV.
- Given the available data, pegylated interferon alfa plus ribavirin is the treatment of choice (see Figure 4 in the original guideline document).
- Clinicians should exercise caution when using interferon/ribavirin combination therapy in patients with cirrhosis or patients receiving highly active antiretroviral therapy (HAART).
- The combined use of didanosine and ribavirin is contraindicated.
- Clinicians should obtain baseline studies to assess liver chemistry and measure complete blood counts, thyroid-stimulating hormone, glucose, quantitative HCV RNA in serum, HCV genotype, and alpha-fetoprotein (only if cirrhotic) before initiating anti-HCV therapy. If the patient is female, the

clinician should perform a pregnancy test due to potential teratogenic effects of HCV treatment.
- Co-infected patients should be referred to a specialist with experience in treating hepatitis C in patients with HIV infection. This specialist should obtain a liver biopsy to assess the extent of liver damage. Based on the results of laboratory tests and the liver biopsy, the specialist should offer guidance and recommendations regarding treatment.

Transplantation

- HIV Specialists should collaborate with transplantation programs to offer transplant as an option for HIV/HCV co-infected patients.

Monitoring and Follow-Up of the HIV/HCV Co-Infected Patient

- Clinicians should obtain a complete blood count and monitor serum ALT at 2- to 4-week intervals in patients receiving anti-HCV therapy (see Table 12 in the original guideline document).
- A quantitative HCV RNA assay should be obtained after 24 weeks of treatment to determine whether the patient is responding to therapy.
- If HCV RNA is undetectable or has decreased $\geq$2 $\log_{10}$ (100-fold) at 24 weeks, treatment should be continued for another 24 weeks (see Figure 4 in the original guideline document). If HCV RNA is detectable with <2 $\log_{10}$ reduction with persistently elevated serum liver enzymes, therapy should be discontinued; if serum liver enzymes have normalized, completing the course of therapy should be considered (see Figure 4 in the original guideline document).
- Clinicians should perform a quantitative HCV RNA assay at the completion of therapy and again 24 weeks later to assess end-of-therapy response and sustained treatment response, respectively.
- A repeat liver biopsy after eradication of HCV infection is not indicated.

CLINICAL ALGORITHM(S)

Clinical algorithms for hepatitis C virus (HCV) testing and for HCV therapy in treatment-naive patients are provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Early identification and treatment of hepatitis C virus (HCV) co-infection
- Eradication of HCV from the serum as determined by undetectable HCV ribonucleic acid (RNA) assay

- Reduction of hepatic inflammation/necrosis
- Decreased disease progression
- Subsequent reduction in hepatocellular carcinoma

POTENTIAL HARMS

False Negative Results

There is a small but measurable false-negative rate for antibody testing in patients who are severely immunosuppressed (CD4 <100 cells/mm^3)

Side Effects of Treatment

- Interferon alfa has significant potential side effects, including flu-like symptoms, fatigue, alopecia, bone marrow suppression, and neuropsychiatric effects, including apathy, cognitive changes, irritability, and depression (see Table 11 in the original guideline document). It is important to recognize that some of these adverse effects may be treatable with antidepressants and colony-stimulating factors for bone marrow toxicity. Side effects are severe enough to require dose reductions in 10 to 40% of patients and discontinuation of treatment in 5 to 10%. Patients treated with interferon may also develop a paradoxical worsening of liver disease, probably due to autoimmune processes, and fatal liver failure has occurred; however, this is a rare event and only occurs in patients with already decompensated liver disease. Therefore, patients with a Childs-Pugh classification of B or C must not be treated. Rising serum alanine aminotransferase (ALT) levels during treatment may be an indication for discontinuation of treatment.
- The most common toxicity of ribavirin is hemolytic anemia, which can be effectively treated with recombinant erythropoietin. Use of erythropoietin to maintain ribavirin dosing is preferential to reducing the dose of ribavirin. In addition, ribavirin is teratogenic and should be used with caution in women of child-bearing age. A monthly pregnancy test should be performed. Also, sexually active men and women taking ribavirin should use two forms of contraception.

CONTRAINDICATIONS

CONTRAINDICATIONS

Absolute Contraindications for Treating Patients with HIV/HCV Co-Infection

- Allergy to interferon/ribavirin
- Autoimmune disorders (e.g., lupus, rheumatoid arthritis)
- Pregnant/nursing women, women unable to practice contraception, or men with pregnant partners
- Severe or uncontrolled psychiatric disease
- Severe cardiac disease (angina, known coronary artery disease [CAD])
- Seizure disorders
- Poorly controlled diabetes (glycosylated hemoglobin [HbA1C] >8.5)

- Decompensated cirrhosis (Childs-Pugh class B or C; see Table 7 in the original guideline document)
- Uncontrolled thyroid disease
- Organ transplantation

Additionally, the combined use of didanosine and ribavirin is contraindicated.

Relative Contraindications for Treating Patients with HIV/HCV Co-Infection

- Hgb <11 g/dL in women; <12 g/dL in men*
- White blood cells <1,500 cell/mm^3*
- Age >65 years
- Ongoing heavy alcohol use

*These are relative contraindications because growth factors may be used to correct them.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (*HIV clinical practice guidelines*, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience
- Define target audience (providers, consumers, support service providers).
    - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
    - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
    - What steps need to be taken to make these activities happen?
    - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?

        - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
        - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
    - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
    - Did the processes and strategies work?
    - Were the guidelines implemented?
    - What could be improved in future endeavors?

IMPLEMENTATION TOOLS

Clinical Algorithm
Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. Hepatitis C virus. New York (NY): New York State Department of Health; 2004 Sep. 13 p. [14 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 (revised 2004 Sep)

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Medical Care Criteria Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Hepatitis C virus. New York (NY): New York State Department of Health; 2003. 15 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 90 Church Street, New York, NY 10007-2919; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Hepatitis C virus. Tables and recommendations. New York (NY): New York State Department of Health; 2004 Sep. 9 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 90 Church Street, New York, NY 10007-2919; Telephone: (212) 268-6108

This guideline is available as a Personal Digital Assistant (PDA) download from the New York State Department of Health AIDS Institute Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 2, 2005. This NGC summary was updated by ECRI on October 18, 2005. This summary was updated by ECRI on January 29, 2007, following the U.S. Food and Drug Administration advisory on erythropoiesis stimulating agents. This summary was updated by ECRI Institute on July 9, 2007, following the FDA advisory on erythropoiesis stimulating agents. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on February 26, 2008 following the U.S. Food and Drug Administration advisory/voluntary market withdrawal of the liquid formulation of Leukine (sargramostim). This summary was updated by ECRI Institute on March 21, 2008 following the FDA advisory on Erythropoiesis Stimulating Agents. This summary was updated by ECRI Institute on August 15, 2008 following the U.S. Food and Drug Administration advisory on Erythropoiesis Stimulating Agents (ESAs).

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Date Modified: 10/6/2008